

# EXHIBIT A

# Guidance to the Fabry Community on the Management of Fabrazyme (agalsidase beta) Supply

## Temporary Conservation of Fabrazyme Supply to Minimize the Impact of the Shortage on the Health of Patients

Guidance prepared by the Fabrazyme Stakeholders Working Group\*, 27 June 2009

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\*Please note that some individuals who participated in the Fabrazyme Stakeholders Working Group are employees of Genzyme and other individuals or their institutions or organizations receive or have received funding from Genzyme for research, educational activities, and other purposes.

# Guidance to the Fabry Community on the Management of Fabrazyme Supply

## Background

Genzyme recently identified a virus (vesivirus 2117) in one of six bioreactors at its Allston manufacturing facility. This virus is not known to cause disease in humans, but it can impair the viability of the non-human CHO cells used to produce Cerezyme® (imiglucerase for injection) and Fabrazyme® (agalsidase beta). While no evidence of the virus has been detected in any of the material or equipment used to produce Fabrazyme, bulk production of both Cerezyme and Fabrazyme has been temporarily halted to allow for sanitization of the entire facility. This interruption of manufacturing at the Allston facility will result in a temporary shortage in the supply of Fabrazyme. If no changes are made in the current patterns of Fabrazyme use, the available supply is expected to be completely depleted in October 2009 and based on current assumptions, the shortage is expected to last approximately 6-8 weeks.

In order to minimize the impact of the supply shortage on the health of patients with Fabry disease, a Fabrazyme Stakeholders Working Group was convened to develop and disseminate guidance recommendations to temporarily decrease the Fabrazyme used over the next few months in an effort to avoid a period of complete depletion. The Fabrazyme Stakeholders Working Group consists of a group of internationally-recognized physicians with deep clinical and scientific expertise in Fabry disease, leaders of the Fabry Support & Information Group and National Fabry Disease Foundation, and representatives from Medical Affairs and Patient Advocacy at Genzyme Corporation (who provided background information and guidance framework, and who coordinated the meeting).

The Fabrazyme Stakeholders Working Group embraces several principles in developing this guidance for temporary conservation of Fabrazyme supply:

- The guidance should be designed to minimize risk for patients
- The guidance should be the same irrespective of commercial or charitable drug access status
- The guidance should be the same irrespective of geography
- The guidance should be based on the best available evidence and experience
- The guidance should take into account the patient's preferences when there are no clear evidence-based differences between options
- The guidance should aim for wide dissemination and compliance
- The guidance should be simple to understand and practical to implement
- Physicians should make the final treatment decisions regarding their patients

## Recommendations

The Fabrazyme Stakeholders Working Group met in Chicago on 27 June 2009 with the objective of formulating recommendations for temporary reductions of Fabrazyme use in an effort to avoid a complete depletion of the medication. This guidance is based on the assumption that these recommendations should be applied only on a temporary, short-term basis, effective immediately.

### Recommendations:

- 1. All patients should reduce their Fabrazyme intake by the equivalent of two doses during the period of time from July 1 to September 30, 2009.**
- 2. This reduction can be achieved in one of the following ways:**
  - a. Two missed infusions, preferably non-consecutive**
  - b. Four infusions at 0.5 mg/kg, i.e. one-half the standard dose**
- 3. Patients participating in clinical trials should adhere to the study protocol.**
- 4. Naive patients or patients returning to therapy can be started on Fabrazyme during this time period and maintained at 1 mg/kg every 2 weeks.**
- 5. The recommendations should be implemented immediately and widely in order to conserve an adequate supply of Fabrazyme.**
- 6. An update will be provided by Genzyme to the FSWG in early August to evaluate progress**
- 7. The recommendations may be subject to change if the guidance is not widely adopted or if Fabrazyme production timelines need to be revised.**
- 8. Ultimately, treatment decisions are at the discretion of the treating physician. Patients should be encouraged to speak with their physicians about the treatment plan appropriate for them.**